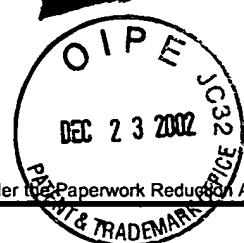


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		Application Number	09/707,655
		Filing Date	11/07/2000
		First Named Inventor	Alan R. Hirsch
		Group Art Unit	1651
		Examiner Name	C. Tate
Total Number of Pages in This Submission		Attorney Docket Number	INS-31061-A

ENCLOSURES (check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Whyte Hirschboeck Dudek S.C. Kristine M. Strothoff
Signature	<i>Kristine M. Strothoff</i>
Date	December 23, 2002

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant : Alan R. Hirsch

Serial No. : 09/707,655

Filing Date : November 7, 2000

For : USE OF ODORANTS TO ALTER BLOOD FLOW TO THE VAGINA, AND
ARTICLE OF MANUFACTURE THEREFOR

Group Art Unit: 1651

Examiner : C. Tate

Docket No. : INS-31061-A

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

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Washington, D.C. 20231

APPELLANT'S REPLY BRIEF

Sir:

This is in response to the Examiner's Answer mailed October 22, 2002, in the above-identified application.

(2) Related Appeals and Interferences.

A related application USSN 09/211,507 is currently under appeal.

(7) Grouping of Claims.

The Examiner's statement is incorrect. As stated in Appellant's Brief at page 3, Claim 25 is *grouped separately* from the remaining claims.

Claim 25¹ is directed to an article comprising an odorant and instructions, and a device for measuring blood flow to the vagina of the female individual and/or means for testing olfactory ability in the female individual.

The remaining claims are directed to articles comprising particular odorant mixtures and instructions for administering the odorant mixture to alter blood flow to the vagina.

(11) Response to Argument.

First of all, throughout the Examiner's Answer, the Examiner repeatedly states that the "Appellant argues that the Examiner asserts..." Appellant is not arguing that the Examiner is asserting various positions. Rather, Appellant is restating the Examiner's arguments from the final Office Action.

The Examiner has not fully considered nor adequately addressed Appellant's arguments. The Examiner has provided no good basis for his position that the claims are not fully enabled and utilize indefinite language.

In reply to the Examiner's Answer at page 6 (first half of 2nd parag.), the claims do not encompass "any undefined odorant and/or non-commercial subjective odorants." The claims on appeal² are limited to articles comprising *specified mixtures of odorants*:

- a mixture of a *licorice-based* odorant and *banana nut bread* odorant
- a mixture of a *licorice-based* odorant and *cucumber* odorant
- a mixture of a *lavender* odorant and *pumpkin pie* odorant
- a mixture of a *baby powder* odorant and *chocolate* odorant

¹ Claim 25. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to alter blood flow to the vagina when inhaled by a female individual;
instructions for administering the odorant to alter blood flow to the vagina; and
at least one of the following:
a device for measuring blood flow to the vagina of the female individual; and
means for testing olfactory ability in the female individual.

² Excluding Claim 25 (see footnote 1).

The claims (including Claim 25) are further limited to *odorants that alter blood flow to the vagina*.³ It is implicit in the claims that the conditions of the recited odorant are not met unless the odorant achieves the recited effect.

In response to the Examiner's Answer at page 6 (second half of 2nd paragr. to page 7), the Examiner's contention that variations in a cucumber odorant according to brand, age/ripeness, a purported and undefined difference in odor between milk chocolate and dark chocolate, etc., is *clearly in error* and does not provide a basis for requiring the claims be limited to specific commercial embodiments.

The Examiner contends that the recited odorants are highly subjective with respect to the actual odors being encompassed on the basis that:

- a given recipe of pumpkin pie or banana nut bread will vary according to the ingredients,
- baby powder odorants will vary by commercial manufacturer,
- a cucumber odorant will vary according to the brand, species, age/ripeness, and geographic location in which it is grown, etc.,
- a licorice-based odorant such as Good and Plenty™ will have a distinct odor from other licorice based products such as anise, and
- a chocolate odorant such as milk chocolate has a distinct odor from dark chocolate.

Each of the odorants recited in the claims will possess a distinct and characteristic aroma or odor that defines the particular odorant.

- A pumpkin pie or banana nut bread odorant will each have a characteristic and recognizable pumpkin pie or banana nut bread odor. Variation of "recipe" is necessarily limited to be within the scope of the aroma that is characteristic of the odorant.
- All baby powder odorants will have a similar characteristic odor that is identified and defined as a baby powder odor — regardless of the manufacturer.
- A cucumber odorant will have a recognizable cucumber odor — regardless of brand, age, etc.
- A licorice-based odorant — exemplified by a Good and Plenty odorant — will not have a distinctive odor from an anise odorant. First of all, anise is a licorice-based odorant — as admitted by the Examiner. Secondly, a Good and Plenty odorant includes licorice extract and anise flavor as component ingredients.
- A chocolate odorant — regardless of whether it is a milk chocolate or a dark chocolate odorant — will clearly have a chocolate odor.

³ The other limitations in Claim 25 are also noted. See footnote 1.

Each of the recited odorants — *regardless of source* — will have a characteristic odor that is within the scope of the aroma that defines the particular odorant as it is understood and employed in the art.

It is well within the ordinary skill in the odorant arts to ascertain non-commercial and other commercial sources of odorants that fall within the scope of the claims other than the particular demonstrated commercial odorants. Indeed, one of ordinary skill in the odorant arts would be able to readily ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma — regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source.

In response to the Examiner's Answer at page 7 (1st full paragr.), the varying effects of the odorant mixtures in altering blood flow to the vagina does not provide a basis for requiring the claims be limited to specific commercial embodiments of odorants.

The Examiner asserts that the claims should be limited to the commercially identified odorants because the use of other odorants would be highly unpredictable between females. The Examiner bases his reasoning on Appellant's results showing that the same mixture of odorants can cause an increased blood flow to the vagina in some females and a decreased blood flow to the vagina in other females.

First — the Examiner has *not* denied the patentability of the claims based on differing effects. Rather, the Examiner requires that the claims be limited to specific commercial odorants described in Appellant's Example.

Variations in effects are described in the Example at pages 16-17 of the specification.^{4,5} This variation in effect is the result of characteristics of the female individual — not variations in

⁴ See results at pages 15, lines 1-19:

Women who found manual genital stimulation arousing showed a 12-percent increase in vaginal blood flow in response to pumpkin pie and lavender, and averaged an 18-percent increase with the Good & Plenty® licorice-based odorant and cucumber combination.

No odors induced sexual arousal in the *women who were not extremely aroused by manual genital stimulation*, whereas many odors inhibited arousal, including male colognes and perfumes, both of which decreased blood flow by 14 percent. *The Good & Plenty® licorice-based odorant and cucumber combination decreased blood flow by 13 percent in that group.*

⁵ See discussion at page 16, line 19 to page 17, line 6.

Individual odorants and odorant mixtures that *increased vaginal blood flow by about 10-30%*, included..., a mixture of a licorice-based odorant and banana nut bread odorant, *a mixture of a licorice-based odorant and*

the odorants. As the Example illustrates, it was the variation in a female's response to manual genital stimulation that showed a variation in effect of the licorice-based odorant and cucumber combination.

Contrary to the Examiner's statement, this does not indicate a highly unpredictable nature of the odorant mixtures upon a given female, and does not provide a basis for requiring the claims to be limited to specific commercial embodiments.

Also at page 7 (1st paragr.), the Examiner newly argues that:

...the nature of the claimed/disclosed invention can be considered to be a female ViagraTM (i.e., those odorants which are disclosed as causing an increase in blood flow to the vagina) since ViagraTM is used to increase blood flow to the penis of a male and there have been countless unsuccessful attempts over the centuries to devise various types of female sexual arousal formulations.

The Examiner has provided no reference or other evidence in support of his unsubstantiated assertion of "countless unsuccessful attempts" to devise female sexual arousal formulations.

Furthermore, the Examiner acknowledged Appellant's Declaration submitted in corresponding USSN 09/211,507, to demonstrate the success and effectiveness of his inventive method in altering blood flow to the vagina.⁶

The Examiner's unsupported assertion *should be given no weight* for requiring the claims to be limited to specific commercial embodiments.

cucumber odorant, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. These individual odorants and odorant mixtures were particularly effective in increasing vaginal blood flow in those female individuals who are positively sexually aroused with masturbation or by manual manipulation of the genitals:

Odorants can also be administered to decrease vaginal blood flow of a female individual and the level of sexual arousal. The odorants and odorant mixtures that caused a decrease in vaginal blood flow by about 10-20% included ...*a mixture of a licorice-based odorant and cucumber odorant, ...These odorants and odorant mixtures were particularly effective in reducing vaginal blood flow in those female individuals who were not sexually aroused with masturbation or by touching or manipulation of the genitals by a partner.*

⁶ See Office Action, mailed October 24, 2001, at page 3: "Based upon Applicant's response and Declaration of July 6, 2001 in copending parent Application No. 09/211,507, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants...act to alter blood flow to the vagina via inhaling an effective amount thereof."

In response to the Examiner's answer at pages 7-8 (bridging paragr.), the disclosure of Doty does not provide a basis for requiring the claims be limited to specific commercial embodiments.

The Examiner cites to Doty (Philadelphia Sensorics, 1983) to show that it would be highly unpredictable to use non-commercial or other commercial sources of odorants based on variables such as occupation, general health, psychological state and age of females.

The Examiner states that (emphasis added):

...although the Doty et al. reference is mainly directed to tests for identifying odorants, the overall teachings of Doty et al. show that, in general, these variables play a role in the ability of a person to perceive a given odor (and also that women and men perceive odors differently with regard to intensity pleasantness, coolness/warmth, irritation, and familiarity...

Accordingly, it would not be reasonable for one of skill in the art to wholly dissociate such variables in the smell perception of an odor from the physiological effect(s) the perceived odor has upon an individual, including a female individual.

It is unclear as to the point that the Examiner is trying to make with this statement.

However, Appellant assumes that the Examiner is asserting that one of skill in the art would consider variables such as occupation, etc. as a basis for a varying physiological effect of the claimed odorant mixtures upon a female individual.

There is no information in Doty about the physiological effects of odorants. Doty merely addresses identification of odors.

As admitted by the Examiner, Doty (Philadelphia Sensorics, 1983) describes a test for identifying odorants (the "Smell Identification Test). According to the test, a male or female subject inhales an odorant and then attempts to identify it. Doty describes (at page 3) conducting five initial experiments to develop the Smell Identification Test™:

Exp. 1: selection of stimuli;

Exp. 2: *examination of influence of variables such as the age, gender, and ethnic background of subjects on the scores of the developed Smell Identification Test™;*

Exp. 3: use of the test to discriminate among person with olfactory disorders;

Exp. 4: determining test-retest reliability; and

Exp. 5: comparison of test scores to results from a traditional detection threshold procedure.

In Experiment 2, male and female subjects were asked to identify (*name*) each of 50 stimulants. A series of multiple regression analyses were performed on the data to determine the influence of age, gender, race and smoking habits on the identification test scores.

At the cited pages 16-18, Doty reported on variations in a person's ability to identify odors based on occupation, general health, and psychological state. Doty also reported that a female's (and male's) ability to smell diminishes with age. (See Tables 1 and 2.)

Appellant's claims are directed to articles comprising specific odorant mixtures that *alter blood flow to the vagina*.

Doty provides no information relating to the physiological effect of odor stimulants. Doty's report of diminished capacity to smell in females with age does not provide any support or indication of a varying physiological effect of odorants between females.

The Examiner has made an interpretation of Doty's disclosure that is clearly unsupported by that reference, and *should be given no weight*.

Doty's disclosure does not provide a persuasive reason why Appellant's articles incorporating non-commercial or other commercial sources of odorants would be highly unpredictable between females.

The Examiner has made a determination of non-enablement based on conclusory statements without persuasive reasons or adequate support, and has failed to weigh all of the evidence before him. Appellant has demonstrated that the disclosure as filed would have enabled Appellant's articles as claimed for one skilled in the art at the time of filing. The Examiner has failed to consider Appellant's specification including the experimental example providing guidance, and what was well known to one of skill in the art.

The Examiner has provided no persuasive reason why the specification does not realistically enable one skilled in the art to practice the invention as broadly as claimed through the use of noncommercial or other commercial sources of the recited odorants. *In re Bowen*, 181 USPQ 48, 51 (CCPA 1974).

Appellant believes that the present disclosure is fully enabling for non-commercial and other commercial sources of odorants, and requests that the Examiner withdraw the rejection.

Finally, in response to the Examiner's Answer at page 8, which addresses Appellant's arguments on the rejection of claims for indefinite claim language under 35 U.S.C. § 112(2), the Examiner has not fully considered Appellant's arguments and supporting evidence.

First of all, it is pointed out that in the Examiner's Answer at page 6 (2nd paragr.), the Examiner emphasized that Claim 25 was *not* rejected under Section 112(2). The stated reasoning that Claim 25 was not rejected for indefinite claim language was:

"...because although the term "odorant" is broad, it is not indefinite, *per se*, since there are numerous well known defined odorants..."

However, the Examiner maintains the rejection of the remaining claims — which recite mixtures of *particular* odorants⁷ — for indefinite claim language.

Based on the Examiner's reasoning that the language of Claims 25 ("an odorant") is not indefinite, the remaining claims, which use the same terminology ("odorant") and further specify certain odorants, are also not indefinite.

Secondly, in response to the Examiner's referral to "*odorants having the unusual functional effects upon females as instantly disclosed/claimed*,"⁸ this is no basis for a rejection of the claims as indefinite or for requiring that the claims are limited to specific commercial embodiments of odorants based on undue experimentation.

The Examiner acknowledged the Declaration submitted in Appellant's corresponding application USSN 09/211,507, in response to the Examiner's rejection of lack of utility and non-enablement in which he challenged the believability of Appellant's method and the data provided in Appellant's experimental examples.⁹ The results of Appellant's experimental examples, shown in Tables I-V, fully support Appellant's finding that odorants can be administered to a female individual to alter blood flow to the vagina. (Specification at pages 12-15.)

The unusual effect provided by Appellant's method and the articles as presently claimed is evidence of the non-obviousness of those claims. It does not support a finding of either indefinite claim language or non-enablement.

⁷ The claims (except for Claim 25) recite cucumber, lavender, banana nut bread, pumpkin pie, baby powder, chocolate, and licorice-based odorants.

⁸ See last sentence on page 8 of the Examiner's Answer. This statement is also repeated numerous times under the Grounds of Rejection at pages 3-4 of the Examiner's Answer.

⁹ See footnote 6.

Third, the claims on appeal employ language known and used in the art and which is of the same scope as the described invention. The language of the claims adequately defines the metes and bounds of the claimed invention.

Appellant has submitted various patents and documents to show the acceptance in the art of the terms "chocolate odorant", etc., as well as the use and construction applied to these terms by the USPTO. Such use demonstrates the acceptance and an understanding of these terms in the art, as well as the construction applied to these terms and understanding of other Examiners in the USPTO.

The terms licorice, cucumber, lavender, pumpkin pie, baby powder, and chocolate odorants have been utilized in various contexts including Applicant's own issued patents as well as other issued patents and publications — *including the cited Doty publication* (see at page 7 listing licorice, chocolate, pumpkin pie odorants), for example.

As such, the Examiner's interpretation of the claims is overbroad in view of how the term is used and understood by one skilled in the art and conflicts with the meaning give to identical terms in other patents from analogous art.

One skilled in the odorant arts reading the claims would readily understand the metes and bounds of those terms in the claims when read in light of the specification, which sets forth examples for such odorants, and in view of the knowledge in the art, as evidenced by Applicant's issued patents and Doty's publication, among others. It is respectfully submitted that the nature and identity of the recited odorants is not ambiguous to one skilled in the odorants arts.

REQUEST

For the reasons stated above, and the reasons presented in Appellant's Brief on Appeal, Appellant believes that the claims on appeal fully comply with the requirement of 35 U.S.C. § 112, and earnestly requests that the final rejection of the claims on appeal be reversed.

Respectfully submitted,



Kristine M. Strothoff, Reg. No. 34,259

Dated: December 23, 2002
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